

April 7, 2003

**Guidance Document to Applicants:
FIFRA Section 18 Pilot Program Concerning (1) the Streamlined Application
Process for Select Repeat Emergency Exemption Requests and (2) the Tiered Evaluation
Criteria for Assessing “Significant Economic Loss”**

This document is intended to provide guidance to State and Federal agencies which submit applications for specific emergency exemption requests under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act under the limited pilot program beginning with the 2003 use season. The Agency is piloting two initiatives related to the emergency exemption process. The pilot initiatives may reduce the burden to both applicants (State and Federal agencies) and the EPA in connection with the preparation and evaluation of exemption requests. The pilot will not diminish health and safety protections, but it is anticipated that actions submitted under the pilot can be processed more quickly by the Agency.

This document explains, in detail, the two areas that will be piloted and describes the steps that applicants should take in order to participate in this pilot program. **The Federal Register Notice and this guidance document contain eligibility criteria that describe the type of exemption requests suitable for the pilot initiatives. The two aspects of the pilot involve different criteria. Applicants should carefully review this document and the Federal Register Notice to determine whether a contemplated exemption request is eligible for the pilot.**

The first area that will be piloted will allow applicants for certain repeat exemptions to re-certify that the emergency conditions which initially qualified for an exemption continue to exist. Under the pilot for this area, the applicants’ own certification that the emergency situation is ongoing, along with their incorporation by reference of their earlier full application, will take the place of the submission of data generally required to support a repeat request for an emergency exemption. In this way, the burden associated with the application process for select repeat requests will be significantly reduced. In order to initiate this area of the pilot immediately, EPA has identified the specific uses (pesticide active ingredient-crop combinations) and states that meet the criteria and are eligible for this aspect of the pilot this year (see Appendix No. 1).

The second area that will be piloted involves revising the analytical methodology and economic data necessary to assess whether a “significant economic loss” will occur. Such evaluations are typically needed to support applications for specific emergency exemption requests. Under the pilot, EPA will assess whether a “significant economic loss” will occur through a tiered approach. Successive tiers will require more data and analysis. However, it is thought that many “significant economic loss” findings can be made, without loss of reliability, using less data and analytical resources (by both the applicant and EPA) than the process currently requires.

There are two sections to this document, one for each of the two initiatives under the pilot. Questions about the pilot, or the section 18 process in general, can be directed to Mr. Dan Rosenblatt, Emergency Response Team at (703) 308-9366 or by e-mail at rosenblatt.dan@epa.gov or Sec-18-Mailbox@epamail.epa.gov.

Section 18 Pilot - Issue No. 1

Streamlined Application Process for Select Repeat Requests

Introduction

The regulations governing section 18 of FIFRA, allow the Agency to issue a specific exemption for “...as long a period as is reasonably expected to be necessary *but in no case for longer than 1 year.*” (40 Code of Federal Regulations C.F.R. 166.28(a)). Therefore, EPA has reviewed exemption requests on a year-to-year basis, and required applicants to submit a complete application, along with all supporting documentation, each year. This requirement has been in place even if the situation is one which could reasonably be expected to recur in subsequent years. However, EPA recognizes that some emergency situations continue until the circumstances which precipitated the emergency somehow change.

In light of these considerations, a streamlined application program is being piloted beginning with the 2003 use season. Under the pilot, for certain eligible repeat requests, applicants will be permitted to certify that the conditions which brought about the emergency situation continue to exist. The applicants’ (i.e. the state or federal lead agency for pesticides) own certification and incorporation by reference of their earlier full application is intended to take the place of a new and complete exemption request. For the group of eligible repeat requests, therefore, it is expected that this pilot program will decrease the burden associated with developing and submitting an application for an emergency exemption for the eligible repeat requests. Additionally, it is anticipated that these changes will lead to less Agency review time and more rapid response on eligible requests, which will better support growers and the public in addressing emergency pest problems.

Under this portion of the pilot program, EPA has identified the uses and states which are eligible, during the 2003 use season, to support a repeat exemption request by the applicants’ own certification that the emergency condition is ongoing. The list of uses and states which are eligible for this portion of the pilot are provided in Appendix No. 1 to this document. In developing the uses included in Appendix No. 1, EPA used the criteria discussed in the Federal Register Notice and reiterated below. All four criteria were measured against the pool of requests submitted during the previous use season.

The criteria are presented here so that applicants and the public can better understand the manner in which the initiatives described in the Federal Register Notice could be applied to existing emergency pest control programs.

I. Eligibility Criteria for Streamlined Application Pilot for Repeat Section 18 Emergency Exemptions

All four of the conditions listed below should be met before an emergency exemption request will be considered eligible for the streamlined application pilot.

1. EPA granted the same exemption the previous year, and it is the second or third year of the request by that applicant. The Agency determined that the situation the previous

year satisfied requirements for an emergency condition [40 CFR 166.3(d)]. A complete application will be required the first year of an exemption for a particular applicant, in order to establish the existence of the emergency. Re-certifications will not be accepted as the basis for an emergency after three years of an exemption to an applicant.

2. The emergency situation can reasonably be expected to continue for longer than one year. Examples of these include situations where a registered product relied upon by growers becomes permanently unavailable; expansion of a pest's range; and, documented loss of efficacy of a registered product. Situations which would not be expected to continue would include a temporary supply problem of a registered product; an isolated weather event; and, a sporadic pest outbreak.

3. The request is not for a new chemical, a first food use, or for a chemical under Special Review. A request that is for a chemical which has never been registered as a pesticide under Section 3 of FIFRA, or has never been registered for a food use, or the chemical has officially been placed under Special Review by the Agency, would not be considered for candidacy for re-certification of the emergency.

4. The requested pesticide is registered for another use and has been designated as "reduced-risk" by EPA for one or more uses. The reduced risk program is explained in PR Notice 97-3. This program offers pesticide manufacturers incentives for developing registration applications for pesticides which are less risky than the alternatives for a given pest problem. A committee of EPA scientists evaluates and selects pesticides and uses which are considered to be reduced risk.

On a case-by-case basis, EPA will review with applicants whether other repeat requests, not listed in Appendix No. 1, meet all of the criteria listed here. Applicants who believe there are additional uses that should be added to Appendix No. 1 should contact the Agency.

II. *Schedule and Purpose of the Pilot Program for the Streamlined Application Process for Repeat Requests*

EPA is initiating this pilot in order to (1) gain experience with specific approaches for modifying the section 18 program and (2) take steps to put into place specific initiatives that have been suggested by key stakeholders. The Agency has determined that it will publish a proposed rule concerning the emergency exemption process. EPA will consider any available information from this pilot as it proceeds with rulemaking. At this time, EPA is reserving the possibility of continuing this pilot program for a time frame that extends beyond the 2003 growing season, modifying the pilot in the future, or ending it following this initial pilot year.

As mentioned in the Federal Register Notice, EPA will use existing avenues, such as the Pesticide Program Dialogue Committee and SFIREG to obtain informal feedback and provide information to stakeholders and the public about experiences gained under this pilot. Prior to the start of the 2004 season, EPA will directly inform applicants about the outcome of the initial year of this pilot and the determination on whether this pilot program will continue in this same fashion. This decision will be based on the experiences of applicants and the Agency concerning this initial year of the pilot and also the recommendations and comments that are submitted to EPA in response to the 60 day public comment period announced by the Federal Register Notice.

III. *Overview of Schedule and Review Cycle for Actions Under the Streamlined Application Pilot*

An emergency exemption request that meets the criteria outlined in the Federal Register Notice will be eligible for streamlined application and “re-certification” of the emergency situation for two years following the initial year of the exemption for that applicant. If an emergency continues beyond three years for an applicant, they will again be required to submit a complete request each year, thereafter, with full supporting documentation described under 40 C.F.R. 166.20. Other applicants will, likewise, be eligible for streamlined application and re-certification in the second and third years that they are experiencing the emergency situation. However, EPA’s initial operational design for this program suggests that long-running emergency exemption uses might not be appropriate candidates for this pilot.

As part of the review of an emergency exemption application, EPA makes a determination about whether the registrant is making adequate progress toward obtaining a full label for the requested use. That evaluation is based on the number of years the use (i.e. the chemical-crop combination) has collectively been sought under the emergency exemption program.

Once the data necessary to support the full registration for a use that is associated with an emergency exemption request are submitted, the Agency puts an explicit emphasis on quickly evaluating those data in hopes of eliminating the need for a long-running emergency exemption request. Nonetheless, there are instances when an emergency use will not receive its registration for a number of years while, simultaneously, the pest problems experienced by the agricultural sector have remained ongoing. In general, EPA might consider that a particular use (i.e. chemical-crop combination) that has been sought for the past six years might be too long-standing to be eligible for inclusion in the streamlined application portion of the pilot.

EPA believes that most all candidates for re-certification can be registered relatively quickly. Pesticide producers should place a high priority on efforts aimed at seeking a full registration for a product that is sought under an emergency exemption. Over the past years, a large number of emergency exemption requests have successfully been eliminated due to registration decisions which make the use available through a full label. Moving forward, this will be a continuing emphasis within the Agency. Decisions on future registration work planning and scheduling will continue to bias and support the review of uses associated with emergency uses. Also, of note, the pilot is limited to reduced risk pesticides. Thus, there is a high likelihood that the registration and regulatory issues associated with obtaining a full registration for the subject use can be addressed. EPA will continue to evaluate this issue in its design and operation of the pilot program and also plans on addressing it in the proposed rule.

The Agency continues to encourage applicants to submit requests for re-certification of the emergency situation with sufficient lead time necessary to process the request in advance of the use season.

EPA will establish time-limited tolerances to support use of a chemical for the appropriate period of time in a situation where the emergency pest problem is ongoing. As is currently the case with all section 18s issued, the applicant is responsible for enforcing all aspects of the emergency program. Also, note that EPA retains the authority to revoke an exemption if necessary (40 C.F.R. 166.35.).

Specific Proposed Time Line for Eligible Repeat Requests

Year #1:

The Applicant will submit a complete emergency exemption application, along with all supporting documentation. EPA will conduct a comprehensive review to determine whether the request meets the regulatory criteria for an emergency, and whether the use would pose acceptable risks to health and the environment. For applications involving the treatment of food, EPA will also determine if the appropriate safety findings can be made with respect to reasonable certainty of no harm to human health as required by the Food Quality Protection Act, and establish any necessary time-limited tolerances.

Years #2 and #3:

For a repeat request in the second or third year for a given applicant, that applicant will have the opportunity to “re-certify” that the emergency situation continues to exist. The applicant must certify in writing that the emergency situation has remained unchanged and is ongoing and, further, that they wish to incorporate by reference the application on file with EPA which supported the emergency use initially. An example “re-certification” letter is included in this guidance as Appendix No. 2.

Additionally, the applicant is required to submit a detailed section 18 exemption pesticide usage report for the previous use season. Information must be included as set forth at 40 C.F.R. 166.32, and the applicant will also address the effectiveness of the exemption program for the previous season.

EPA would review the “re-certification” submitted by the applicant, as well as the most recent risk evaluations for the proposed use, and consider whether any alternatives have become available, to ensure that the requested use still meets the criteria for approval. If these conditions have remained the same, and the use pattern is unchanged, the Agency’s review time is expected to be significantly reduced.

Note: If the use pattern for the second and third year is modified in any way, the applicant must clearly state so in the repeat request. A change in the use pattern will likely require additional review to reassess the estimated risk associated with the use. Any changes which may increase exposure will require that the risk be re-evaluated by EPA, and may undercut the ability of the applicant to receive an expedited decision. Such changes may include, but are not limited to: increased application rate or number of applications, additional method of application, changes to pre-harvest or re-entry intervals, or increase in total number of acres to be treated, change in counties or geographic area, and other changes in directions for use.

If the use pattern is changed additional documentation must be submitted along with the certification letter that will support the proposed change. At a minimum the applicant must submit revised section 18 use directions. However, additional information may be required based on the proposed change. For example, a change in the application rate or the PHI may require the time-limited tolerance to be revised. Yet, even though change in the use pattern will likely prevent the Agency from fully expediting the request through the re-certification program, the applicant can still re-certify that emergency conditions still exist, and need not submit a complete application addressing the existence of the emergency.

If the use pattern is the same as in the first year, applicants may include a separate certification that their requested use pattern has not changed in the re-certification year, and incorporate by reference all use pattern specifications submitted in a previous application or applications. This certification of an unchanged use pattern will aid in expediting the Agency's decision.

Year #4 and beyond:

In the fourth and subsequent years of an exemption to a particular applicant, a complete application will again be required for EPA's comprehensive review to determine whether it meets the criteria for an emergency exemption. Additionally, after the first 3 years of use, EPA will consider whether adequate progress toward registration is being made [40 C.F.R. 166.25(b)(2)(ii)].

Key Considerations for the Streamlined Application Pilot

| Factors to be Considered by Applicant | Factors to be Considered by EPA |
|--|--|
| <ul style="list-style-type: none"> - consider whether the situation is an ongoing emergency (> 1 year) - address whether any alternatives have become available - assess experience from the first year of exempted use, and whether it met the needs of the situation | <ul style="list-style-type: none"> - assess whether risk to human health and the environment is acceptable or has changed - evaluate progress that is being made toward registration of the exempted use - confirm Applicant's assertion that no alternatives have become available - consider whether the Applicant is requesting any change in the use pattern from previous year, and if so, the effect on risk |

Appendices Numbers 1-3 Support the Streamlined Application Pilot for Eligible Repeat Requests:

Appendix No. 1: List of eligible uses and states.

Appendix No. 2: Proposed generic certification letter from applicant to EPA indicating the ongoing nature of the emergency pest situation.

Appendix No. 3: Example model format of EPA authorization of a repeat exemption that can be re-authorized under the pilot.

Section 18 Pilot: Issue No. 2

Alternative Means of Supporting “Significant Economic Loss” Determinations for Emergency Exemption Requests Based on Tiered and Streamlined Economic Data

Introduction

EPA is initiating a pilot program concerning its approach for determining significant economic loss, in the context of FIFRA Section 18 emergency exemptions. This pilot program is motivated by three factors. First, the Agency hopes to reduce the burden of data collection and analysis on the part of the States and the Agency in cases where a decision can be made with less information, thus speeding decisions for these cases and permitting more resources to be devoted to more complex situations. Second, the Agency would like to increase transparency and establish more consistent measures of economic loss. Third, the Agency would like to focus the determination of losses due to emergencies on the losses caused by urgent and non-routine pest problems and not confound the issue with price volatility that has sometimes made the criterion of significant economic loss more difficult to apply.

In lieu of the established practice involving net revenue methodology which relies on five historic years of yield, price, cost, and revenue data, the Agency is announcing a pilot project whereby it will use a more flexible, tiered approach for determining significant economic loss, intended to streamline data and analytical requirements. An analysis of past Section 18 requests suggests that this approach will not cause a significant change in the overall likelihood of a significant economic loss finding, but may, in many cases, lead to savings to both applicants and EPA from reduced data and analytical burdens. In particular, these assessment methodologies can reduce or eliminate the need for production cost data that is often difficult to obtain and often inappropriate for use. Further, the tiered system will be more flexible in using price data, especially when historical averages do not reflect the current situation.

Whereas the existing method generally requires detailed historical data, under the pilot approach the analytical burden for determining significant economic loss is divided into three successive tiers. If the pest situation does not appear likely to result in a significant economic loss based on the first tier analysis, it may qualify based on further analysis in succeeding tiers. Each additional tier requires more data and involves more analysis on how the emergency affects profitability. Each tier has a quantitative threshold that will generally apply to all emergency exemption applications. In rare cases the Agency may also make a significant economic loss (SEL) finding based on conditions that do not neatly fit the criteria for three tiers.

Similar to the pilot offered for repeat requests, only emergency exemption applications which request use of “reduced-risk” pesticides will be eligible to present “significant economic loss” data under this alternative tiered method for evaluating economic loss. For this reason, applicants should especially consider new first time requests under section 18 for this area of the pilot. Applicants “opt in” to this portion of the pilot program. Repeat requests would not necessarily, be good candidates for this portion of the pilot because a “significant economic loss” finding will have already been made for the use under the existing “net revenue” assessment model. Nonetheless, in order to gain experience with this new methodology, applicants may support repeat requests, provided the requested pesticide has been designated and registered by EPA as “reduced risk” for one or more uses, by submitting economic data that is responsive to one of the three tiers described in the Federal Register Notice and in this document. The list of pesticide active ingredients that are considered reduced risk is provided as Appendix No. 4.

Emergency exemption requests that are supported by economic data described in this pilot initiative continue to

be subject to appropriate health and environmental standards under the section 18 regulations and the statutory provisions which govern pesticide use and food safety.

This document summarizes the Agency's positions and policies regarding the evaluation of significant economic loss. It does not address other issues associated with emergency exemptions, and it is not intended to supplant the Section 18 regulations at 40 CFR part 166. It is meant to clarify certain parts of the existing regulations, to clarify how the Agency will analyze data and determine significant economic loss, and to serve as additional guidance to Federal and State agencies submitting Section 18 emergency exemption requests.

I. *Demonstration of Significant Economic Loss*

EPA defines “significant economic loss” as a substantial reduction in expected profitability of crop production in the area affected by the emergency. 40 CFR § 166.3(h). As an emergency, the pest situation causing the losses could not have been anticipated and addressed through the regular registration process and must fall outside the bounds of the normally expected pest populations. Such a situation might arise due to abnormal weather conditions, unexpected resistance to usual pest control practices, or loss of a pest control product due to regulation, market disruption or a marketing decision by the product source.

A. *Cause of an expected loss*

According to the regulations at 40 CFR § 166.3(h), only losses caused by the emergency conditions are relevant in determining expected economic losses. Losses due to changes in the output market do not qualify, nor do losses due to conditions other than the pest situation. For example, losses due to abnormal weather conditions cannot be addressed by pesticide policy, even if those losses also cause an unexpected pest situation. Only those losses directly attributable to the pest can be claimed. That is, if a drought were to result in a pest outbreak, the emergency would be the pest outbreak and the baseline yield would be that expected under a drought situation but without the pest.

B. *Evaluating the significance of an economic loss*

EPA has been evaluating the significance of an anticipated economic loss by determining if net revenues per acre for the current year fall within the normal range of variation, defined as grower profits over the most recent five years. If net revenues fall within the historical range, the expected loss is not considered by the Agency to be significant, since it would not exceed what would be expected as a result of normal fluctuations over a number of years. However, if prices for the commodity fluctuate widely over time, growers face a higher standard of loss and may be inadvertently penalized when pest problems result in higher than normal yield losses.

EPA believes a better system would be to determine the significance of economic losses by comparing the situation that would be expected in the absence of the emergency situation to the situation expected to occur. The tiered system sets relatively high thresholds of loss in lower tiers that, if verified, will lead to a finding of significance with only biological information or a minimal amount of economic data. A lower threshold of loss is set for the final tier that will require no more data than is currently demanded.

1. *Tier 1, Yield Loss*

Tier 1 is based on crop yield loss and is a quantity-based measure. EPA will conclude that a significant economic loss will occur if the projected yield loss due to the emergency condition is verified to be 20%

of expected yields or greater. The yield loss threshold in Tier 1 will be the same for all crops and regions. This threshold is set at a level such that a loss which exceeds the threshold would generally also meet the thresholds in Tiers 2 and 3, if the additional economic data were submitted and analyzed. Therefore, for large yield losses it is not necessary to separately estimate economic loss, which requires detailed economic data. Yield losses are measured as the difference between expected yields in the absence of the emergency and yields under the emergency condition when using the best available, registered alternative.

2. *Tier 2, Economic Loss as Percentage of Gross Revenues*

For situations with yield losses that do not meet the yield loss criterion for Tier 1, EPA will evaluate estimates of economic loss as a percent of gross revenue in Tier 2. In addition to yield losses there may be other impacts that affect economic loss, including quality losses and changes in production costs, including pest control, harvesting, sorting and processing. EPA will conclude that a significant loss will occur if the projected losses due to the emergency condition are verified to be 20% of expected gross revenues or higher. This threshold will be the same for all crops and regions. Quality losses occur when damage results such that the commodity fails to meet the market standards for a high-value segment (*e.g.*, export or fresh market) and must be sold in a lower value outlet (*e.g.*, domestic or processed market). Quality losses can occur without loss in quantity or can occur in conjunction with yield losses. This tier will also consider losses due to higher production costs. Higher production costs could include additional pest control costs, for example, mechanical weeding, or additional harvest costs, for example, sorting into different grades. However, these costs must be a result of the emergency before the expenses can be included in the projected loss.

3. *Tier 3, Economic Loss as Percentage of Net Revenues*

For situations in which losses do not meet the criteria for Tiers 1 and 2, EPA will evaluate estimates of economic loss as a percent of net revenue in Tier 2. Economic losses are defined as in Tier 2. EPA will conclude that a significant loss will occur if the projected losses due to the emergency condition are 50% of expected net revenues or higher. This threshold will be the same for all crops and regions. For this purpose, the Agency defines net revenue as gross revenues less variable operating costs (purchased inputs and hired labor). The Agency considers only variable operating costs because these costs are easier to measure and document than fixed costs, such as overhead and depreciation of machinery, and because they are likely to be more reflective of short-term impacts due to emergency conditions.

4. *Other considerations*

The Agency recognizes that in certain situations, significant economic losses may not be demonstrated using the approach outlined above. It is the applicant's responsibility to explain all relevant issues and provide justification for an alternative estimate of losses.

For example, in evaluating the significance of an economic loss for production activities, the Agency may also consider whether the loss could affect the long-term financial viability expected for the activity. If the emergency situation does not lead to immediate economic losses but can be shown to significantly affect the life-span of a perennial crop (*e.g.*, an orchard or vineyard) or the ability to continue to cultivate an annual crop (*e.g.*, permanent establishment of a soil-borne pathogen) such that significant economic loss is likely in the near future, the Agency may grant the requested exemption. Multi-crop pest management strategies, where treatment would be better applied to pests on one crop to avoid damage to another crop, can also be considered with proper data.

II. *Emergency Exemption Applications*

The EPA will base its determination of yield and/or economic loss on the expected or average losses per acre anticipated to occur on affected acreage (the area for which the emergency exemption is requested), not the maximum possible losses. The Agency believes that as a matter of public policy, the average is the appropriate measure with which to balance the benefits accruing from the use of pesticides with any human or ecological risks that might arise.

A. *Documentation of the Emergency*

The application must include an explanation of the events that brought about the emergency pest pressures (weather conditions, resistance development, pesticide cancellation, *etc.*). Claims of abnormal pest or disease pressure must be documented with data or written testimony of qualified experts.

B. *Documentation of Yield Loss (Tiers 1 and above)*

The EPA would prefer that the requests for an emergency exemption be based upon the expected or average yield and/or economic losses anticipated to occur on affected acreage (the area for which the emergency exemption is requested), not the maximum possible losses. If no estimate of average losses can be made, the agency requests both maximum possible losses and that loss that is most frequently observed (the mode of the distribution). If available, the minimum yield loss anticipated on the affected acreage can be helpful in describing the distribution in losses that may result from the emergency situation. Yield loss estimates may be sufficient for a finding of significant economic loss at Tier 1, if they are verifiably equal to or greater than 20% of the expected yields, or the estimates may form the basis for findings at later stages in the review.

Applications should include the yield that would be expected if no emergency existed, or the baseline yield. This estimate may be based on a historical average or other information. The former is likely to be easier to document. If based on other information, it should be documented that the estimate is for the most likely yield and not the maximum possible. Yield losses can be expressed in absolute terms or as percentage of the expected yield. Losses incurred as a result of the emergency should reflect only the losses that would be expected if growers use the best available (registered) means of control.

Loss estimates must be verifiable. The Agency would prefer to see comparative product performance studies of the efficacy or yields of currently registered pesticides, if any, and potential alternatives. If unavailable, noncomparative product performance studies of various pesticides compared to untreated control plots can also be used to verify yield loss claims. Economic injury studies documenting the relationship between pest populations and yield loss may be acceptable, particularly if no alternative control method is available. At the Tier 1 level, the Agency will not usually accept informal monitoring of pest damage and associated yield losses or expert opinion unless well documented and independently verifiable. Such studies may be acceptable in conjunction with economic data verifying gross or net revenue losses.

C. *Documentation of Economic Loss and Gross Revenues*

If a request cannot be granted solely on the basis of yield loss, because losses are below the threshold or are based on data that does not meet verification standards, it will be reviewed at Tier 2, provided sufficient economic data have been included. The Agency defines economic losses as originating from one or more of three sources: yield or quantity losses, quality losses that reduce the price received, and

changes in production costs due to the emergency. These losses are compared to the gross revenues that would be expected without the emergency situation, that is, the baseline gross revenues. Losses of 20% or more meet the criteria for significant economic loss.

Baseline gross revenues are calculated by multiplying the baseline yield (see Section B, above) with the expected price: $GR_0 = P_0 \cdot Y_0$. The expected price may be calculated as the historical average or some other price if it is justified as more appropriate. Examples of acceptable prices are the futures price for the commodity, contract price or current market prices. The source of these prices should be documented, for example, USDA statistics or market reports. In all cases, the application should consider any government price supports, for example, as established in the 2002 Farm Bill, to determine the value of the commodity to the producer.

The impact of yield loss on gross revenue is straightforward. The percentage loss of revenues is equal to the percentage loss of yield when no price changes resulting from the emergency are anticipated.

Economic losses can also result from changes in production costs, including additional pest control costs and higher harvesting and sorting costs, which would not occur in the absence of the emergency. These extra production costs, including alternative chemical, biological or mechanical measures, can be documented by economic studies or other verifiable sources. An example is provided in Table 1. Suppose losses due to a new pest infestation could be as high as 60% with no control, but may be mitigated by a marginally effective registered alternative, which would normally be used against a different pest at a different growth stage. The alternative costs \$100/acre including application costs. According to studies, losses with the alternative could be as high as 30%, with most acreage suffering about 10% losses. Average losses for the affected acreage is estimated at 15%. Economic losses are calculated at \$370/acre (\$270/acre due to yield losses and \$100/acre in additional costs) and represent over 20% of baseline gross revenues.

Table 1. Example of economic loss due to yield (quantity) losses and additional pest control costs.

| | Baseline | Emergency | Change |
|---|------------|------------|--------|
| Yield (ton/acre) | 15.0 | 12.8 | -15.0% |
| Price (\$/ton) | \$120.00 | \$120.00 | |
| Gross Revenue (\$/acre) | \$1,800.00 | \$1,530.00 | -15.0% |
| Additional Pest Control Costs (\$/acre) | | \$100.00 | |
| Economic Loss (\$/acre) | | \$370.00 | |
| Economic Loss/ GR_0 | | 20.6% | |

Sources: Yield and Price data from State Statistical Service (date), yield losses from studies conducted at State Agricultural Experiment Station (researchers, dates), additional pest control costs from estimates by local applicators (documentation included in request).

Note: Shading denotes calculated figures.

Calculation of quality impacts may be more complicated. The baseline price (P_0) should be calculated as a weighted average of the prices of different grades or categories (P_i , where the grades are denoted i). The weights are the percent of yields that usually are sold in each grade, that is

where Y_i is the quantity per acre in grade i and Y_0 is the total quantity per acre. The usual distribution of yields between grades can be documented through historical data. The distribution between grades due to the emergency should be documented in the same fashion as yield losses discussed above. The emergency price (P_E) is calculated using the weights calculated as a result of the emergency, with the grade prices held constant.

Table 2 provides an example of calculating gross revenue losses with combined yield and quality losses due to a pest outbreak in fruit where the produce may be sold to the fresh market, processed (canning) and juice. In this example, yields are reduced 10%, according to studies at the Agricultural Experiment Station. However, 25% of fruit that would normally be sold in the fresh market and 20% of fruit normally sold to processors suffers pest damage such that it does not make grade and is culled for juice. From this information, new weights are calculated and the average price per ton for the fruit is calculated under the emergency situation. The result is a 13% decline in price. Taken together with the reduced yield, gross revenues are calculated to decline by almost 22%. The economic loss is calculated as the difference in gross revenue, $GR_0 - GR_E$, where $GR_E = P_E \cdot Y_E$.

Table 2. Example of economic loss due to both yield (quantity) and price (quality) losses.

| | Baseline | Emergency | Change |
|--|------------|------------|--------|
| Yield (tons/acre) | 16.3 | 14.7 | -10.0% |
| Yield, fresh (tons/acre) | 8.2 | 6.1 | -25.0% |
| Weight | 50.0% | 41.7% | |
| Price (\$/ton) | \$360.00 | \$360.00 | |
| Yield, processed (tons/acre) | 6.5 | 5.2 | -20.0% |
| Weight | 40.0% | 35.6% | |
| Price (\$/ton) | \$220.00 | \$220.00 | |
| Yield, juice (tons/acre) | 1.6 | 3.3 | 105.0% |
| Weight | 10.0% | 22.8% | |
| Price (\$/ton) | 30.00 | 30.00 | |
| Average Price (\$/ton) | \$271.00 | \$235.06 | -13.3% |
| Gross Revenue (\$/acre) | \$4,417.30 | \$3,448.27 | -21.9% |
| Economic Loss (\$/acre) ($GR_0 - GR_E$) | | \$969.04 | 21.9% |

Sources: Yield and Price data from State Statistical Service (date), weights calculated from usage figures (State Statistical Service), yield losses from study conducted at State Agricultural Experiment Station (researcher, date).

Note: Shading denotes calculated figures.

D. *Documentation of Net Revenues*

Requests that cannot be granted at Tiers 1 and 2 will be considered against a standard of losses as a percentage of net cash revenues, provided sufficient data are provided. Economic losses are calculated as in Part C, above, as a combination of yield (quantity) losses, quality losses affecting the price received, and additional pest control costs. If these losses are shown to be 50% of net cash revenues or more, the Agency will find that a significant economic loss has occurred. For these purposes, the Agency defines net cash revenues as the difference between gross revenues and variable operating expenses. Variable operating expenses include purchased inputs and hired labor, but do not include fixed operating costs such as depreciation of machinery and infrastructure or amortized establishment costs. The Agency believes that these costs are most likely to be affected by short-term emergency situations. Further, fixed costs per acre may be highly heterogeneous across farms, depending on size and diversification. Finally, the Agency wishes to avoid problematic issues arising from negative net returns that have sometimes appeared in past requests. If growers are unable to cover their variable operating costs in the baseline scenario, the Agency will question the economic rationale for production.

Many Land Grant institutions publish cost of production or crop budgets. However, these studies may include fixed costs deemed inappropriate for use in this situation or may not be completely accurate for the specific area suffering the emergency. Some, for example, may be more reflective of high-input producers than typical growers. Any changes in budget figures should be accompanied by an explanation as to the reason for the changes. Likewise, not all institutions publish studies for all commodities, but if neighboring states' budgets are reflective of growers' costs, those data are likely to be adequate.

Table 3 presents an example of a calculation of losses as a percentage of net revenues. In this scenario, informal monitoring suggests losses averaging around 25% on affected acreage, using a marginally effective alternative that costs \$20/acre. Economic losses are calculated to be about \$222.50/acre. This yield loss would be sufficient for Tier 1, except for the fact that the data are not easily verifiable. Additional economic data are needed. Operating costs are shown to be about \$520/acre, leaving net cash revenues of \$290/acre as the baseline. Losses therefore represent over 75% of net cash revenues, and support a finding of significant economic loss.

Table 3. Example of losses as a percentage of net revenues.

| | Baseline | Emergency | Change |
|---|----------|-----------|--------|
| Yield (ton/acre) | 6.0 | 4.5 | -25.0% |
| Price (\$/ton) | \$135.00 | \$135.00 | |
| Gross Revenue (\$/acre) | \$810.00 | \$607.50 | -25.0% |
| Additional Pest Control Costs (\$/acre) | | \$20.00 | |
| Economic Loss (\$/acre) | | \$222.50 | |
| Operating Costs (\$/acre) | \$520.00 | \$520.00 | |
| Net Cash Revenue (\$/acre) | \$290.00 | \$67.50 | |
| Economic Loss/Net Cash Revenue | | 76.7% | |

Sources: Yield and Price data from State Statistical Service (date), yield losses from informal monitoring of affected fields (contact, dates), additional pest control costs from estimates by local applicators (documentation)

included in request), operating costs from cost of production survey by Land Grant Institution (researcher, date).

Note: Shading denotes calculated figures.

E. *Other Information*

The Agency recognizes that certain situations that impose significant economic losses may not be captured by the analyses outlined above. For example, the Agency acknowledges that failure to control pests may not result in immediate yield losses but could lead to future losses, as in the case of perennial crops weakened by pest damage. In this situation, biological and economic data relevant to establishing expected long-term profits and changes in long-term profits due to a pest outbreak will be considered. We will also consider cases where control of a pest in one crop avoids damage to another crop as part of an Integrated Pest Management strategy.

If these guidelines are not relevant to the applicant's situation, the applicant must explain why and provide an alternate analysis, with supporting documentation, to demonstrate that significant economic losses are the result of the emergency condition.

III. *Emergency Exemptions for New Crops*

Diversification of U.S. agriculture to improve income and respond to new market opportunities results in the introduction of new crops. Because of their recent introduction, there are often few or no pesticides registered on these crops. However, the Section 18 process is not the appropriate mechanism to obtain a pesticide for the control of a routine, expected pest problem, despite the lack of registered alternatives. Prior to introduction, potential pest problems should be identified and growers who undertake production of a new crop are assumed to have accepted the risks associated with such a venture. Only those situations involving a pest not previously known to affect the crop or an abnormal variation in the population of a known pest would be considered non-routine by the Agency.

Historical yield, price and production cost data are not usually available for recently introduced crops or varieties. The new tiered approach allows for more flexibility in accepting appropriate estimates, but these estimates should focus on most likely yields and prices, rather than the maximum possible.

Appendix No. 1

Uses and States Eligible for the Streamlined Application Pilot for Repeat Emergency Exemption Requests for 2003 Use Season.

For the 2003 use season, EPA has identified uses and states eligible for the streamlined application process for repeat requests. The uses and states listed below have been determined to meet the criteria discussed in the Federal Register Notice and this guidance document. EPA has determined that the states listed may submit a streamlined application and invites them, where necessary, to certify that the section 18 use will be needed to address an ongoing emergency pest situation that is anticipated for the 2003 growing season using the sample letter in Appendix 2 as a suggested guide.

Table 1: Uses and States Eligible for the Streamlined Application Pilot for “Re-certification” of Emergency Conditions Under the Section 18 Pilot Program for 2003.

| Chemical | Site | States |
|---------------------|---------------------|----------------------------------|
| bifenazate | tomato | Colorado, Texas, Virginia |
| carfentrazone ethyl | vegetable, fruiting | Florida |
| fenpyroximate | hop | Idaho and Washington |
| fludioxonil | pomegranate | California |
| indoxacarb | cranberry | Massachusetts |
| methoxyfenozide | soybean | Louisiana, Arkansas, Mississippi |
| pyriproxyfen | vegetable, legume | Florida |
| tebufenozide | sweet potato | Mississippi |
| tebufenozide | grass, pasture | Vermont and Maine |
| tebufenozide | grape | Virginia |

Appendix No. 2

Example format of submission from the applicant “re-certifying” the continuation of an emergency condition for the eligible uses.

The Xyz State Department of Agriculture requests a specific emergency exemption under the provisions of section 18 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, for use of (chemical), formulated as (product name (EPA Reg. No. xxx-xx), on (crop) to control (pest). This is the (#) year the Xyz State Department of Agriculture has requested this use. The Xyz State Department of Agriculture asks that this specific exemption request be processed as an expedited repeat request as the Department certifies that emergency conditions continue to exist for (pest) on (crop). The Xyz State Department of Agriculture incorporates by reference and relies on the application previously submitted to EPA under (insert ee number) to support this exemption request. *(An optional second certification similar to the following can be added, where appropriate).* In addition, Xyz State Department of Agriculture further certifies that pesticide applications will be made in accordance with, and incorporates by reference, all the use pattern provisions of our initial specific exemption application for this use submitted in (insert year) and the Agency’s authorization letter of (insert date) for (insert ee number).

Sincerely,

Designated State Official

Appendix No. 3

Example format for EPA authorization responding to eligible application submitted under the pilot program for the streamlined application process for repeat emergency exemption requests.

Commissioner
 Xyz State Department of Agriculture
 Main Street
 City, State 00000

Attn: State Contact

Fax: (—)-----

Date Issued: June 10, 2003
Date Effective: July 1, 2003
Expiration Date: September 10, 2003
Report Due: March 10, 2004
File Symbol: 03-xx-13
Year Number: 2nd Year (4th Year Overall)

The Environmental Protection Agency hereby re-authorizes a specific exemption under the provisions of section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to the Xyz State Department of Agriculture for the use of (chemical name), formulated as (trade name), on (commodity name) to control (pest). In a letter dated June 1, 2003, the Xyz State Department of Agriculture re-certified that the emergency condition still existed and that there were no changes to the use directions as approved in last year's authorization, including, but not limited to, the use rate, type of application, number of acres, PHI, geographical restrictions, etc.

Xyz State Department of Agriculture will ensure that pesticide applications will be made in accordance with all of the provisions of the specific exemption application submitted in (insert year) and the Agency's authorization letter of (insert date) for (insert ee number). It is also responsible for providing information in accordance with 40 C.F.R. 166.32. This information must be submitted to EPA headquarters and the EPA regional office. The EPA shall immediately be informed of any adverse effects resulting from the use of this pesticide in connection with this exemption.

This is the second year that the Agency has issued this exemption to the Xyz State Department of Agriculture and the first year it has been re-authorized. The Xyz State Department of Agriculture will be allowed to re-certify this exemption for one additional year after which a full application must be submitted to the Agency for comprehensive review.

Director, Registration Division,

Date: _____

Appendix No. 4

*Conventional Pesticide Active Ingredients Eligible for the Section 18 Pilot Initiative
Concerning an Alternative Means for Establishing “Significant
Economic Loss”*

Reduced Risk Ingredients

| | |
|---------------------|---|
| acetamiprid | macalaya extract |
| alpha-metolachlor | mefenoxam |
| azoxystrobin | mesotrione |
| | methoxyfenozide |
| bifenazate | methyl anthranilate |
| buprofezin | |
| | novaluron |
| carfentrazone-ethyl | |
| cyhalofop-butyl | prohexadione-calcium |
| cyprodinil | pymetrozine |
| | pyriproxyfen |
| diflubenzuron | |
| diflufenzopyr | spinosad |
| s-dimethenamid | |
| | tebufenozide |
| Ecolyst | trifloxystrobin |
| | |
| fenamidone | zoxamide |
| fenhexamid | |
| fenpyroximate | |
| fluazinam | |
| flucarbazone-sodium | |
| fludioxonil | |
| flumiclorac-pentyl | |
| | |
| glyphosate | |
| | |
| hexaflumuron | |
| hymexazol | |
| | |
| imazamox | *** EPA will continue to apply appropriate |
| imazapic | regulatory and statutory standards to any emergency |
| imazethapyr | exemption request involving these chemicals. |
| indoxacarb | |
| | |
| lambda-cyhalothrin | |

Biological, Microbial and Other Ingredients Eligible for the Section 18 Pilot Initiative Concerning an Alternative Means for Establishing “Significant Economic Loss”

Floral Attractants/plant Volatiles

Anise, oil of
Mustard, oil of
Citronella, oil of yr in question
Indole
Lavandin oil
Jasmine, oil of
Lemon grass, oil of
Eucalyptus, oil of
Cinnamaldehyde
1,2,4-Trimethoxybenzene
3-Phenyl-2-propenol
Orange, oil of
(Z) cis-1-octen-3-ol
2-Phenylethyl propionate (Nuranone)
Eugenol
Bergamont, Oil of
Geraniol
2-Cyclopenten-1-one, 2-hydroxy-3-methyl (maple lactone)

Plant Growth Regulators and Herbicides

Ethylene
Gibberellic acid
Gibberellic Acid, monopotassium salt
Acetic Acid
Indole-3-butyric Acid
1,4 Dimethyl-napthalene
Kinetin (N6 furfuryladenine)
Cytokinin
N6-Benzyladenine
Gibberellin A4 Mixt with Gibberellin A7
Chitosan
Sodium 5-nitroguaiacolate
Sodium o-nitrophenolate
Sodium p-nitrophenolate
Aminoethoxyvinylglycine
Pelargonic acid

1-methylcyclopropene
Lactic acid
Lysophosphatidyl-ethanolamine
Corn Gluten Meal

Natural Insect Growth Regulators

Isopropyl (2E,4E)-11-methoxy-3,7,11-trimethyl-2-4-dodecadienoate
Isopropyl (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2-4-dodecadienoate
2-Propynyl (S-(E,E))-3,7-11-trimethyl-2,4-dodecadiene
Azadirachtin
Ethyl (2E,4E,7S)-trimethyl-2,4-dodecadienoate

Pheromones

Lauryl alcohol
Myristyl alcohol
(E,E)-8,10-Dodecadien-1-ol
German cockroach Pheromone
(E)-5-Decenol
(E)-5-Decenol Acetate
(Z,Z)-3,13-Octadecadien-1-ol acetate
(E,Z)-3,13-Octadecadien-1-ol acetate
(1R-cis)-1-methyl-2-(1-methylethenyl) cyclobutaneethanol
(Z)-2-(3,3-Dimethylcyclohexylidene) ethanol
(E)-(3,3-Dimethylcyclohexylidene) acetaldehyde
(Z)-(3,3-Dimethylcyclohexylidene) acetaldehyde
(Z,E)-7,11-Hexadecadien-10yl acetate
(Z,Z)-7,11-Hexadecadien-10yl acetate
7,11-Hexadecadienol-1-ol, acetates
cis-7,8-Epoxy-2-methyloctadecane
(R,Z)-5-(1-Decenyl) dihydro-2(3H)-Furanone
(Z)-11-Hexadecenal
(Z)-4-Tridecen-1-yl acetate
(E)-4-Tridecen-1-yl acetate
(Z)-8-Dodecen-1-yl acetate
(E)-8-Dodecen-1-yl acetate
(Z)-8-Dodecen-1-ol
3,7,11-Trimethyl-2,6,10-dodecatriene-1-ol
3,7,11-Trimethyl-1,6,10-dodecatriene-3-ol
(Z)-11-Tetradecenyl acetate
(Z)-9-Dodecenyl acetate
(E)-11-Tetradecen-1-ol, acetate
(E)-11-Tetradecen-1-ol
(Z)-11-Tetradecenyl acetate
(E)-11-Tetradecen-1-ol, acetate
(Z)-11-Tetradecenyl acetate

(Z)-9-Tricosene
(E)-9-Tricosene
(Z)-9-dodecenyl acetate
3-methyl-2-cyclohex-1-one (MCH)
Z-9-Tetradecen-1-ol

Z,E,9,12-Tetradecadien-1-yl
 Verbenone
 (zz)-11,13-Hexadecadienol
 4-(or5-)Chloro-2-methylcyclohexanecarboxylic acid,
 1,1-dimethyl ester
 (Z)-11-Hexdecenyl Acetate
 (E)-9-Dodecen-1-ol acetate

Repellents

Dried blood
 Capsaicin
 Red Pepper
 Methyl Salicylate
 Meat Meal
 Putrescent whole egg solids
 Methyl anthranilate
 Allium sativum (Garlic oil)
 Linalool
 Fish oil
 Cedarwood oil
 Iron phosphate
 .beta.-Alanine, N-acetyl-N-butyl-,ethyl ester (IR 3535)
 p-methane-3,8-diol
 Mint Oil
 Thyme (herb)

Miscellaneous biochemicals

Neem oil
 Clarified hydrophobic neem oil
 Soybean oil
 Castor oil
 Jojoba Oil
 Sodium bicarbonate
 Potassium bicarbonate
 Sodium lauryl sulfate RED multi divisional
 Liquid Nitrogen
 Ground sesame stalks
 Poly-N-acetyl-D-glucosamine
 Polyoxin D znc salt
 Kaolin
 Canola Oil
 Monobasic potassium phosphate
 Formic acid
 Hydrogen peroxide
 Harpin Protein
 Phosphorous Acid
 Reynoutria sachalinensis (Milsana)

4-allyl anisole
 Dipotassium phosphate
 Sucrose octanoate

Registered Microbial Pesticides

Bacteria

Spores of Bacillus popilliae
 Bacillus thuringiensis subsp. kurstaki
 Agrobacterium radiobacter K84
 B. thuringiensis subsp. israelensis
 B. thuringiensis . Berliner
 B. thuringiensis subsp. tenebrionis
 P. fluorescens A506
 P. fluorescens 1629RS
 P. syringae 742RS
 B. thuringiensis subsp. kurstaki EG2348
 B. thuringiensis subsp. kurstaki EG2424
 B. thuringiensis subsp. kurstaki EG2371
 B. sphaericus
 B. subtilis GBO3
 B. thuringiensis subsp. aizawai GC-91
 B. thuringiensis subsp. aizawai
 Streptomyces griseoviridis K61
 B. thuringiensis subsp. kurstakiBMP123
 B. subtilis MBI 600
 P. syringae ESC 10
 P. syringae ESC 11
 B. thuringiensis subsp kurstaki EG7841
 B. thuringiensis subsp kurstaki EG7826
 B. thuringiensis subsp kurstaki M200
 B. thuringiensis subsp kurstaki EG7673 col. toxin
 Bacillus cereus Strain BP01
 Paecilomyces fumosoroseus Apopka strain 97
 B. thuringiensis subsp isaelensis st g2215
 Pseudomonas aureofaciens st Tx-1
 B. subtilis amyloliquefacie ns strain fzb24
 Bacillus subtilis qst 713
 Pseudomonas chlororaphis St 63-28

Yeast

Candida oleophila I-182

Fungi

Phytophthora palmivora MWV
 Colletotrichum gloeosporioides f.sp.aeschynomene ATCC
 20358
 f.sp. aeschynomene ATCC 20358

Trichoderma harzianum ATCC 20476
 Trichoderma polysporum ATCC 20475
 Gliocladium virens G-21
 Trichoderma harzianum Rifai KRL-AG2
 Lagenidium giganteum
 Metarhizium anisopliae ESF1
 Ampelomyces quisqualis M10
 Beauveria bassiana GHA
 Beauveria bassiana ATCC 74040
 Gliocladium catenulatum Strain J1446
 Trichoderma Harzianum Strain T-39
 Coniothyrium minitans St con/m/91-08
 Killed fermentation solids & solubles of Myrothecium
 verrucaria
 Myrothecium verrucaria
 Beauveria bassiana st 447
 Pseudozyma flocculosa

Protozoa

Nosema locustae

Viruses

Heliothis Nucleopolyhedrosis virus (NPV)
 Douglas fir tussock moth NPV
 Gypsy moth NPV
 Beet armyworm NPV
 Cydia pomonella Granulosis virus
 Indian Meal Moth Granulosis Virus
 Anagrapha falcifera NPV (Celery Looper Virus)

Non-viable Microbial Pesticides--(Engineered)

Bt subsp. kurstaki delta-endotoxin in K P. fluorescens
 in killed P. fluorescens
 Bt subsp. san diego delta-endotoxin in K P. fluorescens
 in killed P. fluorescens
 Bt CryIA(c) & Cry I(c) delta-endotoxin in K P fluorescens
 in killed P. fluorescens
 Bt K CryIC in killed pseudomonas
 Agrobacterium radiobacter Strain K1026